

Evaluation of an Expandable Stem Total Hip Replacement System

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Abstract

The expandable nail concept uses high-pressure saline to inflate the diameter of a cylindrical implant to achieve fixation within the medullary canal of bone. Expandable nails are used clinically in a number of fracture management applications and have been more recently developed as a femoral component for total hip replacement. In this study, the expandable total hip replacement stem design was evaluated, specifically testing to determine if acrylic cement can be used in place of saline for permanent expansion, to observe the amount of stem subsidence after cyclic loading, and to document if stem expansion creates untoward stresses in the femur. The results included that the expandable femoral component could be expanded with cement if careful control of cement viscosity is used with a modified filling technique. Neither untoward hoop strains nor stem subsidence was found in tests with the cadaveric femurs. Bench testing has confirmed the stability of these stems. In addition, the substitution of cement for saline would make the construct permanent, avoiding the risk of deflation and loosening. The concept of an expandable femoral prosthesis is appealing and would have many potential clinical applications. The need for cemented stems or the more difficult and costly "Ling technique" could be avoided with their use in tumor surgery, hip fracture

management, and total hip replacements associated with osteoporosis or a patulous femora in both primary and revision settings.

The expandable nail concept, consisting of a crenulated, metal cylindrical shell that expands in diameter when pressurized with saline (~1000 psi), has been used for intramedullary nail fixation of upper and lower extremity fractures.¹⁻⁵ Although early clinical experience demonstrated the utility of this technology for these applications, there is concern over the possibility of nail deflation, with one case being reported in the orthopaedic literature.⁴ Recent biomechanical evaluations of the expandable nail have examined the stability of the peg of an expandable hip fracture fixation construct and compared its humeral fracture fixation with other intramedullary nail designs.^{2,5-7}

Recently, an expandable femoral component for total hip replacement with an inflatable distal stem body was developed (Fixion[®] Hip System, Disc Orthopaedic Technologies Inc, Monroe Township, New Jersey) (Fig. 1). The component is inserted into the prepared proximal femur in its deflated, reduced diameter state. When in the proper orientation, the distal stem is expanded under controlled pressure. Expansion results in a press-fit, with the endosteum providing an axially and rotationally stable construct.⁴ The theoretical advantages of this design include the ability of the expandable stem to conform to the natural variability in internal contours of the proximal femoral shaft, providing improved fixation, and the simplicity of using one component size for all patients.

In the evaluation of the expandable femoral component, we examined several research questions. First, is it possible to inflate the stem with self-curing bone cement (methylmethacrylate) to prevent deflation over time? Second, what is the subsidence stability of the stem, and how does it compare to press-fit stems? And finally, are there dangers such as femoral splitting or high, internal medullary pressures

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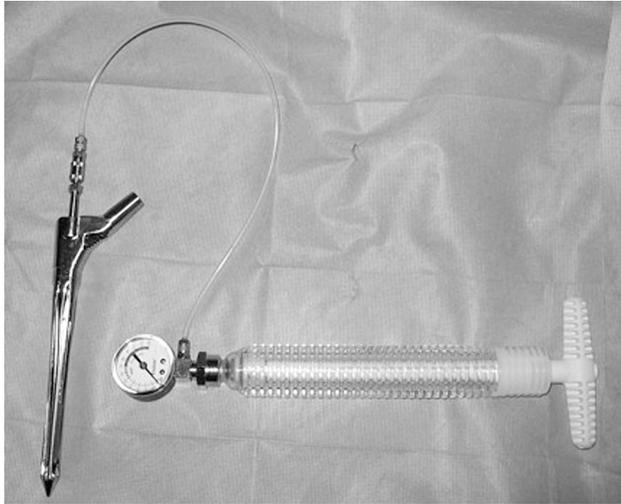


Figure 1 Expandable femoral component (Fixion® Hip System femoral components, Disc Orthopaedic Technologies Inc., Monroe Township, New Jersey) with inflation pump attached to a one-way valve in the proximal stem neck.

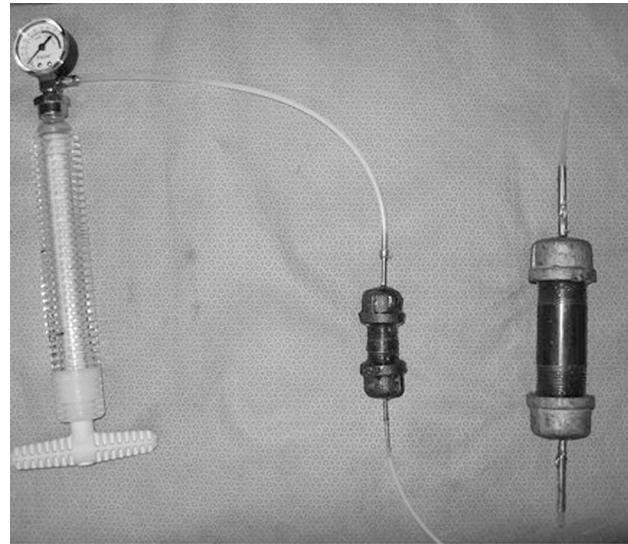


Figure 2 Adaptation made to the pump system, with the addition of a 5 cc steel chamber (left) to facilitate cement expansion of the femoral component. The 40 cc steel chamber (right) proved to be too large, with the pump unable to evacuate this space.

associated with the implantation of this stem design?

Materials and Methods
Cement Injection

Fixion® Hip System femoral components were obtained as the implant for evaluation. These implants are manufactured from stainless steel. Their stem bodies have a ribbed expandable section whose nominal diameter is 12 mm in the deflated state; they can be inflated to a diameter of 19 mm. Grooves present on the distal part of the stem allow for improved axial stability following expansion. Expansion of the stem with normal saline (water in the current experiments) occurs to a pressure of 70 bars (~1000 psi) with use of a disposable plastic pump. A one-way valve is positioned proximally on the stem neck to prevent saline leakage from the stem body. Testing demonstrated that the 70 bars of pressure needed for full stem expansion required a pump injection of 3.5 ml of normal saline.

To evaluate the usefulness of inflating the stem with cement to prevent deflation over time, adaptations were made to the disposable pump. Because of unknown reactivity of methylmethacrylate with the pump material, a steel chamber was added to the system (Fig. 2). Initial experiments with chilled cement introduced into an auxiliary 40 cc steel chamber attached to the pump were not successful, as the pump could not evacuate this space and monomer was found to affect the pump. The steel chamber size was reduced to 5 cc and water was introduced into the entire system (tubing, chamber, and pump) before purging the pump and filling the chamber, once more, with cement until it was seen in the tubing past the chamber.

A low viscosity cement (Spineplex™, Stryker, Inc., Mahwah, New Jersey) was used and chilled to 5° C in a refrigerator to decrease viscosity. Experiments were performed with Spineplex™, varying the monomer to powder ratios in order to further reduce the viscosity. A 25% increase in monomer

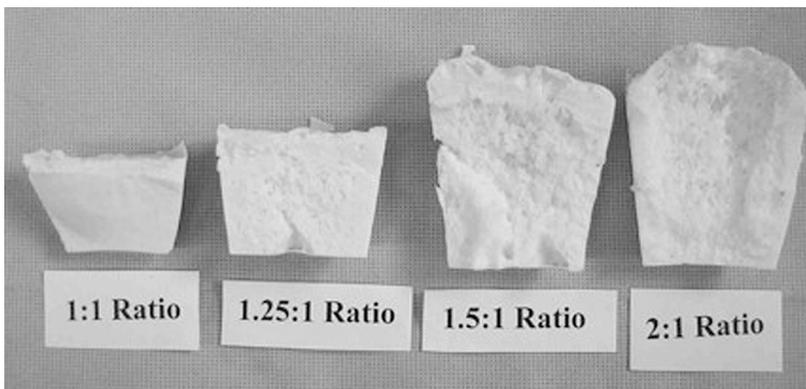


Figure 3 Variation of methylmethacrylate monomer to powder ratio in an effort to reduce cement viscosity for stem expansion. A 25% increase in monomer resulted in a low viscosity cement without significantly affecting polymerization expansion and heat generation.



Figure 4 Anteroposterior radiographs of the expanded femoral components in 13.5 mm (left) and 15 mm (right) diameter medullary cavity specimens. Insufficient lateral reaming resulted in the implant in the 15-mm diameter specimen being inserted and expanded in a tilted position.

was used, as this did not significantly affect polymerization expansion and heat generation (Fig. 3).

Stem Subsidence

Three stems were implanted into embalmed cadaveric femurs, with medullary canals prepared to 12 mm, 13.5 mm, and 15 mm in diameter. The stems were then expanded with water to 70 bars (Fig. 4). The femoral condyles were removed and equal lengths of the femoral shafts of each specimen were potted with a low-melting temperature alloy in 6 cm square steel tubes that were 20 cm long. Throughout the experiment, dessication was avoided by using saline-soaked gauze during testing and keeping each specimen tightly wrapped in airtight double bags.

Biomechanical evaluation of each specimen was then performed by securing the potted bone/implant constructs in a vise at 25° adduction in the coronal plane and at neutral in the sagittal plane to simulate a one-legged stance. An Instron 2000 Universal Material Testing Machine (Instron, Canton, Massachusetts) was used for loading, applying a polished flat applicator that permitted free movement of the modular femoral head when loaded. Each specimen was subjected to cyclic axial loading with 750 N at a frequency of 3 Hz for 10,000 cycles. Stem subsidence was continuously



Figure 5 Evaluation of stem subsidence during cyclic axial loading.

measured with an electronic displacement gauge affixed to the inferior modular head and to the femoral shaft (Fig. 5). Specimens were, subsequently, cyclically loaded with 1500 N at a frequency of 3 Hz for an additional 10,000 cycles, with subsidence continuously measured. For each cyclic loading scenario, stem displacements were recorded at 10, 100, 1000, and 10,000 cycles.

To determine the holding ability of the distal portion of the femoral component, 5 cm of proximal femoral bone was removed to expose the stem neck. The heads were then reloaded with 1500 N for an additional 10,000 cycles and stem displacements similarly measured.

Femoral Strains Associated with Stem Expansion

For this experiment, an expandable femoral stem was inserted into an embalmed cadaveric femur with a 12-mm medullary cavity, prior to subsidence testing. Two strain gauges (EA-06-063AP-120; Micro-Measurements, Inc., Raleigh, North Carolina) were mounted (one anterior-medial, one anterior-lateral) with epoxy on the outer cortex of the femur, 4 cm above the distal tip of the stem. The gauges were oriented to measure hoop strains as a function of pump pressure during stem expansion (electronic gauge bridge P-1300; Micro-Measurements, Inc., Raleigh, North Carolina).

Results

Cement Injection

After injection, cement had to be cleaned from the stem attachment fixture and stem insertion site. The stem expanded to 15 mm to 16 mm from an initial 12 mm. When the stem was transversely sectioned to observe the extent of cement penetration, no cement was found in the distal portion of

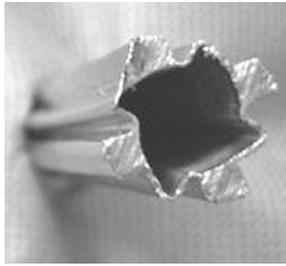


Figure 6 Transverse sectioning of the femoral component stem body after expansion using cement demonstrated no cement in the distal portion of the expanded stem, only a small plug proximally.

the expanded stem, only a small plug proximally (Fig. 6). We calculated the internal volume of the expanded stem as 8.5 cc; this means that, even with 3.5 ml of injected fluid, compressed air is the major component filling the stem.

Stem Subsidence

Subsidence testing of the three expandable femoral components demonstrated minimal inferior displacement for each specimen after 10,000 cycles of 750 N load (Table 1). Increasing the applied load to 1500 N for another 10,000 cycles did not significantly increase the amount of stem subsidence seen in the expanded 12-mm or 13.5-mm diameter femoral components. A fracture of the femur at the distal portion of the stem in the 15-mm diameter specimen was seen after 4228 cycles of 1500 N loading. This occurred secondary to the component being tilted during implantation, increasing the stress experienced laterally at the stem tip.

Reloading the specimens with 1500 N for 10,000 cycles after removal of bone from the proximal femur led to the 12-mm diameter specimen displacing a further 0.01 mm and the 13.5-mm diameter specimen displacing 0.03 mm.

Femoral Strains due to Stem Expansion

Femoral stem expansion resulted in minimal strain detected on the medial and anterior femoral cortices (Table

2). Slightly more strain was seen with the anterior strain gauge, compared to that seen with the medial strain gauge during expansion.

Discussion

Our evaluation of the expandable femoral component demonstrated that liquid cement can be used to expand the stem. This technique requires careful attention to the procedure and control of cement viscosity. The use of cement for expansion as a replacement for saline makes the construct permanent and avoids the risk of deflation and loosening. However, when expanded with cement, the component cannot be deflated to facilitate removal if revision becomes necessary. Additionally, we did not see any indication that high injection pressures adversely affected methylmethacrylate polymerization.

Component subsidence is initially discouraged by the proximal, medial “teeth” on the stem neck and grooves along the stem body that dig into the bone. Even when all bone supporting the proximal stem (unexpanded portion) is removed, the expandable region of the stem provides strong resistance to subsidence. The amount of subsidence observed in our biomechanical evaluation were similar to that seen with press-fit stem designs.^{8,9} Torsional stability was not measured in our testing of the components, but we were unable to detect any motion when manual torsional loads were applied to the stems.

Expansion of the stem did not create large internal pressures transmitted to the femur. Crenulations provide venting of the medullary cavity during inflation. This is likely due to the large area of contact between the stem and medullary wall uniformly distributing applied internal loads due to stem expansion. Unlike a standard press-fit stem, where the stem taper creates high proximal stresses and occasional fracture, the expandable stem is inserted in its deflated state.^{8,9} Stem inflation was not sufficient to “correct” an improperly implanted varus component, resulting in a femur fracture during cyclic loading due to increased stress at the distal tip of the implant.

Table 1 Subsidence Testing

Femur Medullary Size (mm)	Inferior Displacement (mm) @ 10,000 cycles, 750 N load	Inferior Displacement (mm) @ 10,000 cycles, 1500 N load
12	0.03	0.02
13.5	0.04	0.03
15	0.14	Femur broke@4228 cycles*

*This stem was tilted during insertion; loading was thus increased medially

Table 2 Femoral Stem Expansion

Pump Pressure-Bars	Medial Gauge-μ“/”	Anterior Gauge-μ“/”
0	0	.0014
50	.001	.0017
60	.001	.0027
70	.002	.0035

Conclusions

Bench testing confirmed the stability of the expandable femoral component design. The substitution of cement for saline would make the construct permanent, avoiding the risk of deflation and subsequent loosening. The concept of an expandable femoral prosthesis is appealing and could have many potential clinical applications.

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